HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

January 21, 1999

WARNING LETTER NO. 99-NOL-11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Donovan Luedke, President
Southern Machine & Tool Works, Inc.
6525 Sunplex Drive
Ocean Springs, Mississippi 39564-8691

Dear Mr. Luedke:

During an inspection of your firm located at 6525 Sunplex Drive, Ocean Springs, Mississippi, on November 12, 20, 23 and December 2, 1998, our investigator determined that your firm manufactures spinal implants. These products are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, *Code of Federal Regulations* (CFR), Part 820, as follows:

- Failure to validate the manufacturing processes with respect to milled spinal implants;

- Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria;

- Failure to establish and maintain adequate procedures for implementing corrective and preventive action. For example, returns are not evaluated to identify existing or potential causes of nonconforming product or other quality problems;

- Failure to establish and implement an adequate complaint handling program. For example, there are no written procedures for receiving, reviewing and evaluating complaints in accordance with the GMP regulation;

- Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements. For example, customer returns and "rework" (e.g., lot [redacted] are not processed according to written procedures;

- Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures. For example, no audits of the quality assurance program have been performed in at least the past two years and no written procedures were available for review; and,

- Failure to establish and implement maintenance, inspection, and adjustment schedules for manufacturing equipment.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all warning letters involving devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for certificates for products for export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Ms. Barbara D. Wright, Compliance Officer, Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosures: FDA 483
21 CFR 820